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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,415	02/20/2007	Anthony Simmons	UTSG:263US	2190

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,415	SIMMONS ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,12-20,22,28-30,36-41,46 and 47* is/are pending in the application.

4a) Of the above claim(s) *28-30,36-41,46 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12-20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 10/30/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-7, 12-20, 22, 28-30, 36-41, and 46-47 are pending. Claims 28-30, 36-41, and 46-47 are withdrawn as being drawn to nonelected inventions. Claims 1-7, 12-20, and 22 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 12/19/2006 has been considered. An initialed copy is enclosed.

Claim Objections

Claims 1-2, 5-6, and 15 are objected to because of the following informalities: the claims contain the acronyms HSV and HIV. While acronyms are permissible shorthand in the claims, the first recitation should include the full recitation followed by the acronym in parentheses. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the antibody" in line 7. There is insufficient antecedent basis for this limitation in the claim. It is not clear whether "the antibody" is the single chain

antibody of claim 6, the second antibody of claim 6, or the structure that would be created by coupling these two antibodies.

Claim 22 recites the limitation "the composition of claim 1" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is drawn to a single chain antibody, not to a composition comprising a single chain antibody.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Burton *et al.* (US Patent 6,376,170, April, 2002; IDS filed 12/19/2006).

The instant claims are drawn to antibodies that specifically bind to an HSV glycoprotein, specifically, to glycoprotein D.

Burton *et al.* disclose single chain antibodies that bind to HSV glycoprotein D (see figure 1 and column 4, lines 7-38).

Claims 1-2, 12-16, 19-20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Burton *et al.* (US Patent 6,156,313, 2000; IDS filed 12/19/2006).

The instant claims are drawn to antibodies that specifically bind to an HSV glycoprotein, specifically, to glycoprotein D.

Burton *et al.* disclose compositions for topical use (including gels) which comprise single chain antibodies specific to HSV glycoprotein D (see column 7, lines 13-34 and column 10, lines 27-40). With regard to claims 13-15 and 22, the claims state that the composition must comprise at least a second single chain antibody (or antibody). The parent claim is drawn to "a" single chain antibody, which refers to a single antibody, and the dependent claims require a second antibody. Therefore, a composition with more than one antibody (even of the same type and binding specificity) meets the limitations of the claims. As Burton *et al.* refer to compositions

containing antibodies (which means more than one), the disclosure of Burton *et al.* meets the limitations of claims 13-15 and 22.

Claims 1-2, 12-16, 19, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tso *et al.* (US Patent 5,932,448, 1999; IDS filed 12/19/2006).

The instant claims are drawn to antibodies that specifically bind to an HSV glycoprotein, specifically, to glycoprotein D.

Tso *et al.* disclose compositions comprising bispecific single chain antibodies that will bind to HSV glycoprotein D (see column 6, lines 30-35 and column 10, lines 35-40). With regard to claims 13-15 and 22, the claims state that the composition must comprise at least a second single chain antibody (or antibody). The parent claim is drawn to "a" single chain antibody, which refers to a single antibody, and the dependent claims require a second antibody. Therefore, a composition with more than one antibody (even of the same type and binding specificity) meets the limitations of the claims. As Tso *et al.* refer to compositions containing antibodies (which means more than one), the disclosure of Tso *et al.* meets the limitations of claims 13-15 and 22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 12-16, 19-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton *et al.* (US Patent 6,156,313, 2000; IDS filed 12/19/2006) in view of Alvarez-Vallina *et al.* (Eur. J. Immunol., 26:2304-2309, 1996).

The instant claims are drawn to antibodies that specifically bind to an HSV glycoprotein, specifically, to glycoprotein D.

Burton *et al.* disclose compositions for topical use (including gels) which comprise single chain antibodies specific to HSV glycoprotein D (see column 7, lines 13-34 and column 10, lines 27-40). With regard to claims 13-15 and 22, the claims state that the composition must comprise at least a second single chain antibody (or antibody). The parent claim is drawn to "a" single chain antibody, which refers to a single antibody, and the dependent claims require a second antibody. Therefore, a composition with more than one antibody (even of the same type and binding specificity) meets the limitations of the claims. As Burton *et al.* refer to compositions containing antibodies (which means more than one), the disclosure of Burton *et al.* meets the limitations of claims 13-15 and 22.

Burton *et al.* differs from the instant invention in that the disclosed single chain antibody does not further comprise a transmembrane region of a cell surface receptor, specifically, a T-cell receptor.

Alvarez-Vallina *et al.* disclose chimeric single chain antibody fragment/CD28 molecules that comprise a T-cell receptor (CD28) and a single chain antibody fragment (see abstract). Alvarez-Vallina *et al.* disclose that said molecule allows effective co-stimulation of T-cells when binding to the antigen recognized by the scFv (see page 2304, column 2, paragraph 2).

It would have been obvious to one of ordinary skill in the art, at the time of invention, to combine the anti-HSV single chain antibody of Burton *et al.* with the T-cell receptor chimera of Alvarez-Vallina *et al.* because such a construct would allows effective co-stimulation of T-cells when binding to HSV.

One would have had a reasonable expectation of success because the methods used by Alvarez-Vallina *et al.* to create the chimera were standard methods known in the art.

Claims 1-2, 5, 12-16, 19-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton *et al.* (US Patent 6,156,313, 2000; IDS filed 12/19/2006) in view of Nicola *et al.* (J. Virol., 72:3595-3601, 1998; IDS filed 12/19/2006).

The instant claims are drawn to antibodies that specifically bind to an HSV glycoprotein, specifically, to glycoprotein D.

Burton *et al.* disclose compositions for topical use (including gels) which comprise single chain antibodies specific to HSV glycoprotein D (see column 7, lines 13-34 and column 10, lines

27-40). With regard to claims 13-15 and 22, the claims state that the composition must comprise at least a second single chain antibody (or antibody). The parent claim is drawn to "a" single chain antibody, which refers to a single antibody, and the dependent claims require a second antibody. Therefore, a composition with more than one antibody (even of the same type and binding specificity) meets the limitations of the claims. As Burton *et al.* refer to compositions containing antibodies (which means more than one), the disclosure of Burton *et al.* meets the limitations of claims 13-15 and 22.

Burton *et al.* differs from the instant invention in that the antibody is only disclosed as binding to HSV glycoprotein D, and not to site VII or site Ib of HSV glycoprotein D.

Nicola *et al.* disclose the importance of various sites on HSV glycoprotein D that are important in blocking infection by the virus. Nicola *et al.* state that antibodies against site Ib and VII blocked entry by the virus into cells (see abstract).

It would have been obvious to one of ordinary skill in the art, at the time of invention, to use single chain antibodies against sites Ib and VII of HSV glycoprotein D because these sites blocked entry into cells.

One would have had a reasonable expectation of success because the generation of libraries of single chain antibodies in order to find antibodies with particular binding specificities is disclosed by Burton *et al.* and is known in the art.

Claims 1-2, 12-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton *et al.* (US Patent 6,156,313, 2000; IDS filed 12/19/2006) in view of Hostetler (US Patent 5,580,571, 1996).

The instant claims are drawn to antibodies that specifically bind to an HSV glycoprotein, specifically, to glycoprotein D.

Burton *et al.* disclose compositions for topical use (including gels) which comprise single chain antibodies specific to HSV glycoprotein D (see column 7, lines 13-34 and column 10, lines 27-40). With regard to claims 13-15 and 22, the claims state that the composition must comprise at least a second single chain antibody (or antibody). The parent claim is drawn to "a" single chain antibody, which refers to a single antibody, and the dependent claims require a second antibody. Therefore, a composition with more than one antibody (even of the same type and

binding specificity) meets the limitations of the claims. As Burton *et al.* refer to compositions containing antibodies (which means more than one), the disclosure of Burton *et al.* meets the limitations of claims 13-15 and 22.

Burton *et al.* differs from the instant invention in that the composition is not disclosed as further containing a nucleoside analog as an antiviral therapeutic agent.

Hostetler discloses topical compositions comprising acyclovir phosphates, which are nucleoside analogs useful for treatment of herpes (see abstract).

It would have been obvious to one of ordinary skill in the art, at the time of invention, to combine a topical composition comprising a single chain antibody that binds to HSV glycoprotein D with a topical composition comprising acyclovir because one would simply have been combining known prior art elements where each element would have performed the same function as it did separately, with predictable results.

Claims 1-2, 6-7, 12-16, 19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tso *et al.* (US Patent 5,932,448, 1999; IDS filed 12/19/2006).

The instant claims are drawn to antibodies that specifically bind to an HSV glycoprotein, specifically, to glycoprotein D.

Tso *et al.* disclose compositions comprising bispecific single chain antibodies that will bind to HSV glycoprotein D (see column 6, lines 30-35 and column 10, lines 35-40). With regard to claims 13-15 and 22, the claims state that the composition must comprise at least a second single chain antibody (or antibody). The parent claim is drawn to "a" single chain antibody, which refers to a single antibody, and the dependent claims require a second antibody. Therefore, a composition with more than one antibody (even of the same type and binding specificity) meets the limitations of the claims. As Tso *et al.* refer to compositions containing antibodies (which means more than one), the disclosure of Tso *et al.* meets the limitations of claims 13-15 and 22.

Tso *et al.* differs from the instant invention in that, while they disclose bispecific antibodies that bind to HSV glycoprotein D, they do not specifically state that both antigen binding portions should be specific for an HSV glycoprotein or another pathogen associated protein.

It would have been obvious to one of ordinary skill in the art, at the time of invention, to produce a bispecific antibody according to Tso *et al.* where both binding portions had specificity against HSV glycoproteins because one would simply be combining known prior art elements with predictable results. Tso *et al.* disclose bispecific antibodies that are specific for multiple molecules, and choosing any one of the disclosed specificities would have been obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645
/Mark Navarro/
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